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8 Attorneys for Defendants  
9 Pfizer Inc. and Warner-Lambert Company LLC

10 UNITED STATES DISTRICT COURT  
11 SOUTHERN DISTRICT OF CALIFORNIA

12 MARILYN BENNETT, SCOTT BENNETT, and ) Case No. 08 CV 0341 LAB LSP  
13 CHAD BENNETT, all individually and as )  
14 successors in interest to the Estate of ALAN )  
15 BENNETT, Deceased, ) **ANSWER TO COMPLAINT ON BEHALF**  
16 ) **OF DEFENDANTS PFIZER INC. AND**  
17 ) **WARNER-LAMBERT COMPANY LLC**  
18 Plaintiffs, )  
19 vs. )  
20 PFIZER, INC., PARKE-DAVIS, a division of )  
21 Warner-Lambert Company and Warner-Lambert )  
22 Company LLC, WARNER-LAMBERT ) Complaint filed: February 21, 2008  
23 COMPANY and WARNER-LAMBERT )  
24 COMPANY LLC, DOES 1-100, inclusive, )  
25 Defendants. )

26 Defendants Pfizer Inc. ("Pfizer") and Warner-Lambert Company LLC, formerly known as  
27 Warner-Lambert Company ("Warner-Lambert"), on its own behalf and on behalf of its  
28 unincorporated division, Parke-Davis (collectively referred to hereinafter as "Defendants"), by their  
undersigned counsel, answer Plaintiffs' Complaint in the above-captioned action (the "Complaint")  
as follows:

**AS TO PRELIMINARY STATEMENT**

1. Deny the allegations in paragraph 1, except deny knowledge or information sufficient  
to form a belief as to the truth of the allegations in paragraph 1 relating to the relationship and legal  
status between Plaintiffs and the Plaintiffs' Decedent, and therefore deny same; admit that Plaintiffs

1 seek the relief stated in paragraph 1, but deny that Plaintiffs are entitled to such relief; and admit that  
2 the United States Food and Drug Administration ("FDA") has approved Neurontin<sup>®</sup> ("Neurontin"),  
3 the brand name for gabapentin, for labeling as safe and effective only as adjunctive therapy in the  
4 treatment of partial seizures in patients with epilepsy and in the management of postherpetic  
5 neuralgia.

6 **AS TO JURISDICTION AND VENUE**

7 2. Paragraph 2 and its subparts assert legal conclusions to which no response is required,  
8 and Defendants therefore deny the allegations in paragraph 2 and its subparts, except admit: (1) that  
9 Pfizer is a Delaware corporation and has its headquarters in the State of New York; (2) that Warner-  
10 Lambert Company was a wholly-owned subsidiary of Pfizer from June 2000 through December 31,  
11 2002, when it was converted into a Delaware limited liability company known as Warner-Lambert  
12 Company LLC with Pfizer as its sole member; (3) that Parke-Davis is an unincorporated division of  
13 Warner-Lambert Company LLC; and (4) upon information and belief, that the parties are diverse  
14 and the amount in controversy exceeds the sum of \$75,000, exclusive of interest and costs.

15 **AS TO PARTIES**

16 3. Deny knowledge or information sufficient to form a belief as to the truth of the  
17 allegations in paragraph 3, and therefore deny same.

18 4. Deny knowledge or information sufficient to form a belief as to the truth of the  
19 allegations in paragraph 4, and therefore deny same.

20 5. Deny the allegations in paragraph 5, except deny knowledge or information sufficient  
21 to form a belief as to the truth of the allegations in paragraph 5 relating to Plaintiffs' knowledge or  
22 beliefs and Plaintiffs' relationship to Plaintiffs' Decedent, and therefore deny same.

23 6. Admit the allegations in paragraph 6.

24 7. Admit the allegations in paragraph 7.

25 8. Admit the allegations in paragraph 8.

26 9. Deny the allegations in paragraph 9, except admit that Parke-Davis was a division of  
27 Warner-Lambert Company from approximately 1978 until approximately June 2000.

1           10.     Deny the allegations in paragraph 10.

2           11.     Deny the allegations in paragraph 11.

3           12.     Deny the allegations in paragraph 12, except admit that Warner-Lambert Company  
4 was a Delaware corporation until December 31, 2002, when it was converted into a Delaware  
5 limited liability company, known as Warner-Lambert Company LLC.

6           13.     Deny the allegations in paragraph 13, except admit that Warner-Lambert Company  
7 was authorized to do business in the State of California until December 31, 2002.

8           14.     Deny the allegations in paragraph 14, except admit that Warner-Lambert Company  
9 was a business entity actually doing business in the State of California until December 31, 2002.

10          15.     Deny the allegations in paragraph 15, except admit that Parke-Davis was a division of  
11 Warner-Lambert Company from approximately 1978 until approximately June 2000.

12          16.     Deny the allegations in paragraph 16.

13          17.     Deny the allegations in paragraph 17, except admit that from December 31, 2002 to  
14 the present Warner-Lambert Company LLC has been a Delaware limited liability company.

15          18.     Deny the allegations in paragraph 18, except admit that Warner-Lambert Company  
16 LLC is a Delaware limited liability company authorized to do business in the State of California  
17 since December 31, 2002.

18          19.     Deny the allegations in paragraph 19, except admit that Warner-Lambert Company  
19 LLC has been a business entity actually doing business in the State of California since December 31,  
20 2002.

21          20.     Deny the allegations in paragraph 20, except admit that Pfizer is and has been the sole  
22 member of Warner-Lambert Company LLC since December 31, 2002.

23          21.     Deny the allegations in paragraph 21.

24          22.     Deny the allegations in paragraph 22.

25          23.     Deny the allegations in paragraph 23.

26          24.     Deny the allegations in paragraph 24, except admit that Warner-Lambert Company  
27 was a wholly-owned subsidiary of Pfizer from June 2000 through December 31, 2002.

28

1           25. Paragraph 25 asserts a legal conclusion to which no response is required, and  
2 Defendants therefore deny the allegations in paragraph 25.

3           26. Deny the allegations in paragraph 26.

4           27. Deny the allegations in paragraph 27, except admit that Warner-Lambert Company  
5 LLC has been a wholly-owned subsidiary of Pfizer since December 31, 2002.

6           28. Paragraph 28 asserts a legal conclusion to which no response is required, and  
7 Defendants therefore deny the allegations in paragraph 28.

8           29. Paragraph 29 asserts a legal conclusion to which no response is required, and  
9 Defendants therefore deny the allegations in paragraph 29.

10          30. Paragraph 30 asserts a legal conclusion to which no response is required, and  
11 Defendants therefore deny the allegations in paragraph 30.

12          31. Paragraph 31 asserts a legal conclusion to which no response is required, and  
13 Defendants therefore deny the allegations in paragraph 31.

14          32. Paragraph 32 asserts a legal conclusion to which no response is required, and  
15 Defendants therefore deny the allegations in paragraph 32.

16          33. Paragraph 33 asserts a legal conclusion to which no response is required, and  
17 Defendants therefore deny the allegations in paragraph 33.

18          34. Paragraph 34 asserts a legal conclusion to which no response is required, and  
19 Defendants therefore deny the allegations in paragraph 34.

20          35. Paragraph 35 asserts a legal conclusion to which no response is required, and  
21 Defendants therefore deny the allegations in paragraph 35.

22          36. Paragraph 36 asserts a legal conclusion to which no response is required, and  
23 Defendants therefore deny the allegations in paragraph 36.

24          37. Paragraph 37 asserts a legal conclusion to which no response is required, and  
25 Defendants therefore deny the allegations in paragraph 37.

26          38. Paragraph 38 asserts a legal conclusion to which no response is required, and  
27 Defendants therefore deny the allegations in paragraph 38.

1           39. Paragraph 39 asserts a legal conclusion to which no response is required, and  
2 Defendants therefore deny the allegations in paragraph 39.

3           40. Paragraph 40 asserts a legal conclusion to which no response is required, and  
4 Defendants therefore deny the allegations in paragraph 40.

5           41. Paragraph 41 asserts a legal conclusion to which no response is required, and  
6 Defendants therefore deny the allegations in paragraph 41.

7           42. Paragraph 42 asserts a legal conclusion to which no response is required, and  
8 Defendants therefore deny the allegations in paragraph 42.

9           43. Paragraph 43 asserts a legal conclusion to which no response is required, and  
10 Defendants therefore deny the allegations in paragraph 43.

11           44. Paragraph 44 asserts a legal conclusion to which no response is required, and  
12 Defendants therefore deny the allegations in paragraph 44.

13           45. Paragraph 45 asserts a legal conclusion to which no response is required, and  
14 Defendants therefore deny the allegations in paragraph 45.

15           46. Paragraph 46 asserts a legal conclusion to which no response is required, and  
16 Defendants therefore deny the allegations in paragraph 46.

17           47. Paragraph 47 asserts a legal conclusion to which no response is required, and  
18 Defendants therefore deny the allegations in paragraph 47.

19           48. Paragraph 48 asserts a legal conclusion to which no response is required, and  
20 Defendants therefore deny the allegations in paragraph 48.

21           49. Paragraph 49 asserts a legal conclusion to which no response is required, and  
22 Defendants therefore deny the allegations in paragraph 49.

23           50. Paragraph 50 asserts a legal conclusion to which no response is required, and  
24 Defendants therefore deny the allegations in paragraph 50.

25           51. Paragraph 51 asserts a legal conclusion to which no response is required, and  
26 Defendants therefore deny the allegations in paragraph 51.

1           52. Paragraph 52 asserts a legal conclusion to which no response is required, and  
2 Defendants therefore deny the allegations in paragraph 52.

3           53. Paragraph 53 asserts a legal conclusion to which no response is required, and  
4 Defendants therefore deny the allegations in paragraph 53.

5           54. Paragraph 54 asserts a legal conclusion to which no response is required, and  
6 Defendants therefore deny the allegations in paragraph 54.

7           55. Paragraph 55 asserts a legal conclusion to which no response is required, and  
8 Defendants therefore deny the allegations in paragraph 55.

9           56. Paragraph 56 asserts a legal conclusion to which no response is required, and  
10 Defendants therefore deny the allegations in paragraph 56.

11           57. Paragraph 57 asserts a legal conclusion to which no response is required, and  
12 Defendants therefore deny the allegations in paragraph 57.

13           58. Paragraph 58 asserts a legal conclusion to which no response is required, and  
14 Defendants therefore deny the allegations in paragraph 58.

15           59. Paragraph 59 asserts a legal conclusion to which no response is required, and  
16 Defendants therefore deny the allegations in paragraph 59.

17           60. Paragraph 60 asserts a legal conclusion to which no response is required, and  
18 Defendants therefore deny the allegations in paragraph 60.

19           61. Paragraph 61 asserts a legal conclusion to which no response is required, and  
20 Defendants therefore deny the allegations in paragraph 61.

21           62. Paragraph 62 asserts a legal conclusion to which no response is required, and  
22 Defendants therefore deny the allegations in paragraph 62.

23           63. Paragraph 63 asserts a legal conclusion to which no response is required, and  
24 Defendants therefore deny the allegations in paragraph 63.

25           64. Paragraph 64 asserts a legal conclusion to which no response is required, and  
26 Defendants therefore deny the allegations in paragraph 64.

1           65. Paragraph 65 asserts a legal conclusion to which no response is required, and  
2 Defendants therefore deny the allegations in paragraph 65.

3           66. Paragraph 66 asserts a legal conclusion to which no response is required, and  
4 Defendants therefore deny the allegations in paragraph 66.

5           67. Paragraph 67 asserts a legal conclusion to which no response is required, and  
6 Defendants therefore deny the allegations in paragraph 67.

7           68. Paragraph 68 asserts a legal conclusion to which no response is required, and  
8 Defendants therefore deny the allegations in paragraph 68.

9           69. Deny the allegations in paragraph 69, except admit that Pfizer's headquarters are in  
10 New York.

11           70. Paragraph 70 asserts a legal conclusion to which no response is required, and  
12 Defendants therefore deny the allegations in paragraph 70.

13           71. Paragraph 71 asserts a legal conclusion to which no response is required, and  
14 Defendants therefore deny the allegations in paragraph 71.

15           72. Paragraph 72 asserts a legal conclusion to which no response is required, and  
16 Defendants therefore deny the allegations in paragraph 72.

17           73. Deny the allegations in paragraph 73, except admit that since June 2000, Pfizer,  
18 directly and/or indirectly through its subsidiaries, has marketed and sold Neurontin.

19           74. Deny the allegations in paragraph 74, except admit that Pfizer, directly and/or  
20 indirectly through its subsidiaries, has marketed and sold Neurontin since June 2000.

21           75. Deny the allegations in paragraph 75, except admit that Pfizer is engaged, directly  
22 and/or indirectly through its subsidiaries, in the business of designing, manufacturing, advertising,  
23 marketing and selling pharmaceutical drugs, and transacts business within the State of California and  
24 contracts to provide goods in the State of California.

25           76. Deny the allegations in paragraph 76.

26           77. Deny the allegations in paragraph 77.

27           78. Admit the allegations in paragraph 78.

1           79.     Deny the allegations in paragraph 79.

2           80.     Deny the allegations in paragraph 80.

3           81.     Deny the allegations in paragraph 81, except admit that Parke-Davis marketed  
4 Neurontin on a date prior to May 2, 2001.

5           82.     Deny the allegations in paragraph 82, except admit that Parke-Davis was a division of  
6 Warner-Lambert Company from approximately 1978 until approximately June 2000, and that until  
7 approximately June 2000, Parke-Davis directly and/or indirectly engaged in the business of  
8 marketing pharmaceutical drugs, including Neurontin, and transacted business within the State of  
9 California and contracted to provide goods in the State of California.

10          83.     Deny the allegations in paragraph 83.

11          84.     Deny the allegations in paragraph 84.

12          85.     Deny the allegations in paragraph 85, except admit that Parke-Davis was a division of  
13 Warner-Lambert Company from approximately 1978 until June 2000 and that until June 2000,  
14 Parke-Davis directly and/or indirectly did and solicited business and engaged in a persistent course  
15 of conduct in the State of California, deriving substantial revenue from goods and products  
16 consumed in the State of California.

17          86.     Deny the allegations in paragraph 86.

18          87.     Deny the allegations in paragraph 87.

19          88.     Deny the allegations in paragraph 88, except admit that Warner-Lambert Company  
20 marketed and sold Neurontin until June 2000.

21          89.     Deny the allegations in paragraph 89, except admit that until December 31, 2002,  
22 Warner-Lambert Company was, directly and/or indirectly, engaged in the business of designing,  
23 manufacturing, advertising, marketing, and selling pharmaceutical drugs and transacted business  
24 within the State of California and contracted to provide goods in the State of California.

25          90.     Deny the allegations in paragraph 90.

26          91.     Deny the allegations in paragraph 91.



1           92. Deny the allegations in paragraph 92, except admit that until June 2000, Warner-  
2 Lambert Company, directly and/or indirectly, did and solicited business and engaged in a persistent  
3 course of conduct in the State of California, deriving substantial revenue from goods and products  
4 consumed in the State of California.

5           93. Deny the allegations in paragraph 93.

6           94. Deny the allegations in paragraph 94.

7           95. Deny the allegations in paragraph 95.

8           96. Deny the allegations in paragraph 96.

9           97. Deny the allegations in paragraph 97.

10          98. Deny the allegations in paragraph 98.

11          99. Deny the allegations in paragraph 99, except admit that since December 31, 2002,  
12 Warner-Lambert Company LLC has done and solicited business and engaged in a persistent course  
13 of conduct in the State of California, deriving substantial revenue from goods and products  
14 consumed in the State of California.

15          100. Deny the allegations in paragraph 100, except admit that since December 31, 2002,  
16 Warner-Lambert Company LLC has done and solicited business and engaged in a persistent course  
17 of conduct in the State of California, deriving substantial revenue from interstate commerce.

18  
19                                   **AS TO BACKGROUND**

20          101. Paragraph 101 does not allege facts to which a response is required, and Defendants  
21 therefore deny the allegations in paragraph 101.

22          102. Paragraph 102 does not allege facts to which a response is required, but to the extent  
23 that a response might be deemed required, Defendants admit the allegations in paragraph 102.

24          103. Paragraph 103 does not allege facts to which a response is required, and Defendants  
25 therefore deny the allegations in paragraph 103.

26          104. Paragraph 104 does not allege facts to which a response is required, and Defendants  
27 therefore deny the allegations in paragraph 104.

1           105. Paragraph 105 does not allege facts to which a response is required, and Defendants  
2 therefore deny the allegations in paragraph 105.

3           106. Paragraph 106 does not allege facts to which a response is required, and Defendants  
4 therefore deny the allegations in paragraph 106.

5           107. Deny the allegations in paragraph 107, except admit that, in 1993, the FDA approved  
6 Neurontin for labeling as safe and effective for adjunctive therapy in the treatment of partial seizures  
7 in patients with epilepsy at dosages of 900 to 1800 milligrams per day.

8           108. Deny the allegations in paragraph 108, except admit that the FDA has approved  
9 Neurontin for labeling as safe and effective only as adjunctive therapy in the treatment of partial  
10 seizures in patients with epilepsy and in the management of postherpetic neuralgia.

11           109. Deny the allegations in paragraph 109.

12           110. Deny the allegations in paragraph 110.

13           111. Deny the allegations in paragraph 111.

14           112. Deny the allegations in paragraph 112.

15           113. Deny the allegations in paragraph 113.

16           114. Deny the allegations in paragraph 114.

17           115. Deny the allegations in paragraph 115.

18           116. Deny the allegations in paragraph 116.

19           117. Deny the allegations in paragraph 117.

20           118. Deny the allegations in paragraph 118, except admit that on May 13, 2004, an  
21 Information was filed against Warner-Lambert Company LLC in the United States District Court for  
22 the District of Massachusetts.

23           119. Deny the allegations in paragraph 119.

24           120. Deny the allegations in paragraph 120.

25           121. Deny knowledge or information sufficient to form a belief as to the truth of the  
26 allegations in paragraph 121, and therefore deny same.

122. Deny the allegations in paragraph 122, except deny knowledge or information sufficient to form a belief as to the truth of the allegations that Plaintiffs' Decedent's physician prescribed Neurontin to treat Decedent's pain, and therefore deny same.

123. Deny the allegations in paragraph 123, except deny knowledge or information sufficient to form a belief as to the truth of the allegations that Plaintiffs' Decedent's physician prescribed Neurontin to treat Decedent's pain, and therefore deny same.

124. Deny the allegations in paragraph 124.

125. Deny the allegations in paragraph 125.

126. Deny the allegations in paragraph 126.

127. Deny the allegations in paragraph 127.

**AS TO FIRST CAUSE OF ACTION**

128. Repeat each and every response to the allegations in paragraphs 1 through 127.

129. Deny the allegations in paragraph 129, except admit only those duties imposed by law but deny the breach of any applicable duties.

130. Deny the allegations in paragraph 130.

131. Deny the allegations in paragraph 131.

132. Deny the allegations in paragraph 132, except admit only those duties imposed by law but deny the breach of any applicable duties.

133. Deny the allegations in paragraph 133.

134. Deny the allegations in paragraph 134.

135. Deny the allegations in paragraph 135.

136. Deny the allegations in paragraph 136.

137. Deny the allegations in paragraph 137.

138. Deny the allegations in paragraph 138.

139. Deny the allegations in paragraph 139.

140. Deny the allegations in paragraph 140, except admit that Plaintiffs seek the relief stated in paragraph 140, but deny that Plaintiffs are entitled to such relief.

**AS TO SECOND CAUSE OF ACTION**

141. Repeat each and every response to the allegations in paragraphs 1 through 140.

142. Deny the allegations in paragraph 142.

143. Deny the allegations in paragraph 143.

144. Deny the allegations in paragraph 144.

145. Deny the allegations in paragraph 145.

146. Deny the allegations in paragraph 146.

147. Deny the allegations in paragraph 147.

148. Deny the allegations in paragraph 148, except admit that Plaintiffs seek the relief stated in paragraph 148, but deny that Plaintiffs are entitled to such relief.

**AS TO THIRD CAUSE OF ACTION**

149. Repeat each and every response to the allegations in paragraphs 1 through 148.

150. Deny the allegations in paragraph 150.

151. Deny the allegations in paragraph 151.

152. Deny the allegations in paragraph 152.

153. Deny the allegations in paragraph 153.

154. Deny the allegations in paragraph 154.

155. Deny the allegations in paragraph 155.

156. Deny the allegations in paragraph 156, except admit that Plaintiffs seek the relief stated in paragraph 156, but deny that Plaintiffs are entitled to such relief.

**AS TO FOURTH CAUSE OF ACTION**

157. Repeat each and every response to the allegations in paragraphs 1 through 156.

158. Deny the allegations in paragraph 158.

159. Deny the allegations in paragraph 159.

160. Deny the allegations in paragraph 160, except refer to the Information for its contents.

161. Deny the allegations in paragraph 161, except refer to the Information for its contents.

162. Deny the allegations in paragraph 162, except refer to the Information for its contents.

- 1 163. Deny the allegations in paragraph 163, except refer to the Information for its contents.
- 2 164. Deny the allegations in paragraph 164, except refer to the Information for its contents.
- 3 165. Deny the allegations in paragraph 165, except refer to the Information for its contents.
- 4 166. Deny the allegations in paragraph 166, except refer to the Information for its contents.
- 5 167. Deny the allegations in paragraph 167, except refer to the Information for its contents.
- 6 168. Deny the allegations in paragraph 168, except refer to the Information for its contents.
- 7 169. Deny the allegations in paragraph 169, except refer to the Information for its contents.
- 8 170. Deny the allegations in paragraph 170, except refer to the Information for its contents.
- 9 171. Deny the allegations in paragraph 171, except refer to the Information for its contents.
- 10 172. Deny the allegations in paragraph 172, except refer to the Information for its contents.
- 11 173. Deny the allegations in paragraph 173, except refer to the Information for its contents.
- 12 174. Deny the allegations in paragraph 174, except refer to the Information for its contents.
- 13 175. Deny the allegations in paragraph 175, and all subparts thereof, except refer to the
- 14 Information for its contents.
- 15 176. Deny the allegations in paragraph 176, except refer to the Information for its contents.
- 16 177. Deny the allegations in paragraph 177, except refer to the Information for its contents.
- 17 178. Deny the allegations in paragraph 178, except refer to the Information for its contents.
- 18 179. Deny the allegations in paragraph 179, except refer to the Information for its contents.
- 19 180. Deny the allegations in paragraph 180, except refer to the Information for its contents.
- 20 181. Deny the allegations in paragraph 181, except refer to the Information for its contents.
- 21 182. Deny the allegations in paragraph 182, except refer to the Information for its contents.
- 22 183. Deny the allegations in paragraph 183, except refer to the Information for its contents.
- 23 184. Deny the allegations in paragraph 184, except refer to the Information for its contents.
- 24 185. Deny the allegations in paragraph 185, except refer to the Information for its contents.
- 25 186. Deny the allegations in paragraph 186.
- 26 187. Deny the allegations in paragraph 187.
- 27 188. Deny the allegations in paragraph 188.
- 28

- 1 189. Deny the allegations in paragraph 189.
- 2 190. Deny the allegations in paragraph 190, and all of its subparts.
- 3 191. Deny the allegations in paragraph 191.
- 4 192. Deny the allegations in paragraph 192.
- 5 193. Deny the allegations in paragraph 193.
- 6 194. Deny the allegations in paragraph 194.
- 7 195. Deny the allegations in paragraph 195.
- 8 196. Deny the allegations in paragraph 196.
- 9 197. Deny the allegations in paragraph 197, except refer to the supplemental NDA and the  
10 letter dated August 26, 1997 referenced in paragraph 197 for their contents.
- 11 198. Deny the allegations in paragraph 198.
- 12 199. Deny the allegations in paragraph 199.
- 13 200. Deny the allegations in paragraph 200, except refer to the letter dated June 29, 2001  
14 for its contents.
- 15 201. Deny the allegations in paragraph 201, except refer to the letter dated July 1, 2002 for  
16 its contents.
- 17 202. Deny the allegations in paragraph 202.
- 18 203. Deny the allegations in paragraph 203.
- 19 204. Deny the allegations in paragraph 204.
- 20 205. Deny the allegations in paragraph 205.
- 21 206. Deny the allegations in paragraph 206.
- 22 207. Deny the allegations in paragraph 207.
- 23 208. Deny the allegations in paragraph 208, except refer to the article referenced in  
24 paragraph 208 for its contents.
- 25 209. Deny the allegations in paragraph 209.
- 26 210. Deny the allegations in paragraph 210.
- 27 211. Deny the allegations in paragraph 211.
- 28

1           212. Deny the allegations in paragraph 212, except admit that sales of Neurontin have  
2 increased since 1999 and deny knowledge or information sufficient to form a belief as to the  
3 percentage of Neurontin prescribed for off-label uses.

4           213. Deny the allegations in paragraph 213.

5           214. Deny the allegations in paragraph 214.

6           215. Deny the allegations in paragraph 215.

7           216. Deny the allegations in paragraph 216.

8           217. Deny the allegations in paragraph 217.

9           218. Deny the allegations in paragraph 218, except admit that sales of Neurontin have  
10 increased since 1998, and deny knowledge or information sufficient to form a belief as to the  
11 percentage of Neurontin prescribed for off-label uses.

12          219. Deny the allegations in paragraph 219.

13          220. Deny the allegations in paragraph 220.

14          221. Deny the allegations in paragraph 221.

15          222. Deny the allegations in paragraph 222.

16          223. Deny the allegations in paragraph 223.

17          224. Deny the allegations in paragraph 224.

18          225. Deny the allegations in paragraph 225.

19          226. Deny the allegations in paragraph 226, except admit that Plaintiffs seek the relief  
20 stated in paragraph 226, but deny that Plaintiffs are entitled to such relief.

21                                   **AS TO FIFTH CAUSE OF ACTION**

22          227. Repeat each and every response to the allegations in paragraphs 1 through 226.

23          228. Deny the allegations in paragraph 228.

24          229. Deny the allegations in paragraph 229.

25          230. Deny the allegations in paragraph 230, except admit that Plaintiffs seek the relief  
26 stated in paragraph 230, but deny that Plaintiffs are entitled to such relief.

**AS TO SIXTH CAUSE OF ACTION**

231. Repeat each and every response to the allegations in paragraphs 1 through 230.

232. Deny the allegations in paragraph 232.

233. Deny the allegations in paragraph 233

234. Deny the allegations in paragraph 234, except admit that Plaintiffs seek the relief stated in paragraph 234, but deny that Plaintiffs are entitled to such relief.

235. Deny the allegations in paragraph 235.

236. Deny the allegations in paragraph 236. Admit that Plaintiffs seek the relief set forth in the WHEREFORE paragraph following paragraph 236, and all of its subparts, but deny that Plaintiffs are entitled to such relief.

**GENERAL DENIAL**

Defendants deny all allegations and/or legal conclusions set forth in the Complaint that have not previously been specifically admitted, denied, or explained.

**AFFIRMATIVE DEFENSES**

Without assuming the burden of proof of such defenses that they would not otherwise have, Defendants affirmatively assert the following defenses:

**FIRST AFFIRMATIVE DEFENSE**

Plaintiffs' Complaint fails to allege facts sufficient to state a cause of action against the Defendants.

**SECOND AFFIRMATIVE DEFENSE**

If Plaintiffs' Decedent suffered injuries as alleged in the Complaint, such injuries arose from, and were caused by, risks, hazards, and dangers knowingly assumed by Plaintiffs' Decedent. Plaintiffs' recovery accordingly is barred or should be reduced by Plaintiffs and/or Plaintiffs' Decedent's assumption of risk.



1 **THIRD AFFIRMATIVE DEFENSE**

2 Plaintiffs' recovery is barred and/or should be reduced under the applicable law because of  
3 Plaintiffs' and/or Plaintiffs' Decedent's contributory negligence or fault and/or comparative  
4 negligence or fault.

5 **FOURTH AFFIRMATIVE DEFENSE**

6 The Defendants are informed and believe and, upon that ground, allege that Plaintiffs' and/or  
7 the Plaintiffs' Decedent's alleged injuries and damages, if any, were caused in whole or in part by  
8 the acts or omissions of third parties over whom the Defendants had no authority or control,  
9 including without limitation, misuse of the subject product by such third parties. Plaintiffs'  
10 recovery, if any, therefore should be apportioned in accordance with the applicable law.

11 **FIFTH AFFIRMATIVE DEFENSE**

12 If the Plaintiffs' Decedent was injured by any product manufactured, sold, or distributed by  
13 the Defendants, those injuries occurred because said product was used for a purpose other than that  
14 for which it was intended, in a manner other than that in which it was intended to be used, and in  
15 disregard of instructions and directions regarding its use. Accordingly, the said injuries and/or  
16 expenses were caused by the unforeseeable alteration, improper handling, or other unforeseeable  
17 misuse of the prescription drug Neurontin.

18 **SIXTH AFFIRMATIVE DEFENSE**

19 Each purported cause of action of Plaintiffs' Complaint is barred by reason of Plaintiffs'  
20 failure to mitigate their alleged damages or losses.

21 **SEVENTH AFFIRMATIVE DEFENSE**

22 The subject product was a prescription pharmaceutical produced and marketed in strict  
23 compliance with FDA regulations and accompanied by FDA-approved directions and warnings.  
24 Accordingly, each purported cause of action of Plaintiffs' Complaint is subject to the limitations  
25 upon the doctrine of strict product liability for purported design defect as set forth in *Brown v.*  
26 *Superior Court* (1988) 44 Cal.3d 1049 and section 402(A), comment k, of the Restatement (Second)

1 of Torts. The Defendants also affirmatively pleads the application of the Restatement (Third) of  
2 Torts: Products Liability, § 6.

3 **EIGHTH AFFIRMATIVE DEFENSE**

4 The prescription drug Neurontin complied with the applicable product safety regulations  
5 promulgated by the United States Food and Drug Administration (the "FDA"). Compliance with  
6 such regulations demonstrates that due care was exercised with respect to the design, manufacture,  
7 testing, marketing and sale of this prescription drug, and that it was neither defective nor  
8 unreasonably dangerous.

9 **NINTH AFFIRMATIVE DEFENSE**

10 The liability of the Defendants, if any, in this action is subject to the limitations set forth in  
11 the Fair Responsibility Act of 1986. (Civ. Code, §§ 1431-1431.5.)

12 **TENTH AFFIRMATIVE DEFENSE**

13 Each and every alleged cause of action of Plaintiffs' Complaint is barred by the applicable  
14 statutes of limitations including, but not limited to, the provisions of sections 335.1, 338, and 343 of  
15 the Code of Civil Procedure, Civil Code section 1783, and Business and Professions Code section  
16 17208.

17 **ELEVENTH AFFIRMATIVE DEFENSE**

18 Each purported cause of action of Plaintiffs' Complaint is barred because the injuries and  
19 damages allegedly sustained by Plaintiffs, if any, were the result of an independent, unforeseeable,  
20 superseding, or intervening cause.

21 **TWELFTH AFFIRMATIVE DEFENSE**

22 The Defendants are informed and believe and, upon that ground, alleges that Plaintiffs'  
23 and/or the Plaintiffs' Decedent's alleged injuries and damages, if any, were the result of pre-existing  
24 or subsequent conditions that are unrelated to any prescription drug that the Defendants designed or  
25 manufactured.

**THIRTEENTH AFFIRMATIVE DEFENSE**

The subject product is a prescription drug available only through physicians. Accordingly, under the learned intermediary doctrine, this Defendants' duty to warn ran only to the Plaintiffs' Decedent's physicians. *See Carlin v. Superior Court*, 13 Cal.4<sup>th</sup> 1104, 1116 (1996). Each purported claim based on failure to warn is subject to the learned intermediary doctrine.

**FOURTEENTH AFFIRMATIVE DEFENSE**

When it was designed, manufactured and distributed, the subject prescription drug conformed to the state of the art and was reasonably safe, and its benefits exceeded any associated risks.

**FIFTEENTH AFFIRMATIVE DEFENSE**

The conduct of Defendants and the subject prescription drug conformed with the Federal Food, Drug and Cosmetic Act, and other pertinent federal statutes and regulations. Accordingly, Plaintiffs' claims that are predicated on state tort law and allege the subject prescription drug to be unsafe, are barred, in whole or in part, by the doctrine of federal preemption and the Supremacy Clause of the United States Constitution, Article IV, clause 2.

**SIXTEENTH AFFIRMATIVE DEFENSE**

The conduct of the Defendants and all their activities with respect to the subject prescription drug have been and are under the supervision of the United States Food and Drug Administration. Accordingly, this action is barred by the doctrine of primary jurisdiction.

**SEVENTEENTH AFFIRMATIVE DEFENSE**

The Defendants are informed and believe and, upon that ground, allege that each purported cause of action of Plaintiffs' Complaint is barred by the equitable doctrines of laches, waiver, good faith, unclean hands, and estoppel.

**EIGHTEENTH AFFIRMATIVE DEFENSE**

Each purported cause of action of Plaintiffs' Complaint is barred because Plaintiffs' and/or Plaintiffs' Decedent's injuries and damages, if any, were caused by an idiosyncratic reaction that was not reasonably foreseeable to the Defendants.

**NINETEENTH AFFIRMATIVE DEFENSE**

Any claims by Plaintiffs relating to alleged communications with regulatory agencies of the United States Government are barred in whole or in part by operation of applicable law, including First Amendment rights to petition the government.

**TWENTIETH AFFIRMATIVE DEFENSE**

The alleged injuries and damages, if any, were the result of unavoidable circumstances that could not have been prevented by any person, including the Defendants.

**TWENTY-FIRST AFFIRMATIVE DEFENSE**

Plaintiffs' Complaint fails to join indispensable parties necessary for the just adjudication of this matter.

**TWENTY-SECOND AFFIRMATIVE DEFENSE**

Plaintiffs' Complaint fails to state a claim against the Defendants upon which relief can be granted for several or joint and several liability.

**TWENTY-THIRD AFFIRMATIVE DEFENSE**

Plaintiffs' Complaint fails to state a claim against the answering Defendants upon which relief can be granted for costs, expenses, pre-judgment interest, or post-judgment interest.

**TWENTY-FOURTH AFFIRMATIVE DEFENSE**

Plaintiffs cannot state a claim with regard to warnings, labeling or promotion of prescription drugs because the remedy sought by Plaintiffs is subject to the exclusive regulation of the FDA.

**TWENTY-FIFTH AFFIRMATIVE DEFENSE**

This court should abstain from adjudicating Plaintiffs' claims against the Defendants related to warnings, labeling and promotion in deference to the interpretation of regulations relating to prescription drug promotion and labeling by the FDA.

**TWENTY-SIXTH AFFIRMATIVE DEFENSE**

Upon information and belief, each item of economic loss alleged in the Complaint was, or with reasonable certainty will be, replaced or indemnified in whole or in part by collateral sources.

**TWENTY-SEVENTH AFFIRMATIVE DEFENSE**

Plaintiffs' Decedent did not detrimentally rely on any labeling, warnings, or information concerning Neurontin.

**TWENTY-EIGHTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims for breach of warranty, express or implied, are barred by the applicable provisions of the California Commercial Code.

**TWENTY-NINTH AFFIRMATIVE DEFENSE**

Plaintiffs' claim for breach of express warranty is barred because Plaintiffs and/or Plaintiffs' Decedent failed to notify Defendants of any alleged breach of warranty within a reasonable time after they discovered or should have discovered any such alleged breach of warranty.

**THIRTIETH AFFIRMATIVE DEFENSE**

Defendants did not sell or distribute the prescription drug Neurontin directly to the Plaintiffs' Decedent, and the Plaintiffs' Decedent did not receive or rely upon any representations or warranties as alleged in the Complaint. Plaintiffs' claims are barred by lack of privity between Plaintiffs' Decedent and Defendants.

**THIRTY-FIRST AFFIRMATIVE DEFENSE**

Plaintiffs' Complaint fails to state a claim against Defendants upon which relief can be granted for punitive or exemplary damages.

**THIRTY-SECOND AFFIRMATIVE DEFENSE**

Plaintiffs' claims for punitive or exemplary damages are barred under the applicable state and federal law. Permitting recovery of punitive or exemplary damages in this case would contravene Defendants' constitutional rights as reserved by the Fourth, Fifth, Seventh, Eighth, and Fourteenth Amendments to the United States Constitution and other provisions of the United States Constitution and the applicable state constitution.

**THIRTY-THIRD AFFIRMATIVE DEFENSE**

Because of the lack of clear standards, the imposition of punitive or exemplary damages against Defendants would be unconstitutionally vague and/or overbroad.

**THIRTY-FOURTH AFFIRMATIVE DEFENSE**

With respect to Plaintiffs' demand for punitive or exemplary damages, Defendants specifically incorporate by reference any and all standards or limitations regarding the determination and enforceability of punitive or exemplary damages awards under California Civil Code sections 3294 and 3295 and other applicable state law.

**THIRTY-FIFTH AFFIRMATIVE DEFENSE**

No act or omission of Defendants was malicious, willful, wanton, or with actual malice, fraud or oppression as defined in California Civil Code section 3294, and Plaintiffs' Complaint fails to state a claim upon which relief can be granted for punitive or exemplary damages. Plaintiffs' Complaint seeks damages in excess of those permitted by law. Defendants assert any statutory or judicial protection from punitive or exemplary damages that is available under the applicable law, and any award of punitive or exemplary damages is barred.

**THIRTY-SIXTH AFFIRMATIVE DEFENSE**

With respect to Plaintiffs' demand for punitive and exemplary damages, Defendants specifically incorporate by reference any and all standards or limitations regarding the determination and enforceability of punitive and exemplary damage awards which arose in the decisions of *BMW of North America Inc. v. Gore*, 517 U.S. 559 (1996), *Cooper Industries, Inc. v. Leatherman Tool Group*, 532 U.S. 424 (2001), *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408 (2003), and *Philip Morris USA v. Williams*, 127 S. Ct. 1057 (2007).

**THIRTY-SEVENTH AFFIRMATIVE DEFENSE**

Plaintiffs and/or Plaintiffs' Decedent have not suffered any actual injury or damages because of the alleged use of Neurontin as sold by Defendants.

**THIRTY-EIGHTH AFFIRMATIVE DEFENSE**

Plaintiffs' Complaint fails to allege fraud with particularity as required under California law.

1 **THIRTY-NINTH AFFIRMATIVE DEFENSE**

2 Plaintiffs' claims are barred in whole or in part because the commercial speech relating to  
3 Neurontin was not false or misleading and is protected under the First Amendment of the United  
4 States Constitution and the applicable provisions of the California Constitution.

5 **FORTIETH AFFIRMATIVE DEFENSE**

6 To the extent applicable, Plaintiffs' claims for damages are barred, in whole or part, by the  
7 doctrines of res judicata (claim preclusion) and/or collateral estoppel (issue preclusion).

8 **FORTY-FIRST AFFIRMATIVE DEFENSE**

9 The activities alleged in the Complaint conformed with all state and federal constitutional  
10 provisions, statutes, regulations, and industry standards.

11 **FORTY-SECOND AFFIRMATIVE DEFENSE**

12 Plaintiffs are not entitled to an award of attorneys' fees in the absence of a contract, statute,  
13 or law authorizing such fees.

14 **FORTY-THIRD AFFIRMATIVE DEFENSE**

15 The conduct of Defendants and all of their activities with respect to the subject product were  
16 fair and truthful based upon the state of knowledge existing at the relevant time alleged in Plaintiffs'  
17 Complaint and, therefore, Plaintiffs' claims under Business and Professions Code sections 17200  
18 and 17500, Civil Code section 1750 et seq., and other statutes and regulations referenced in the  
19 Complaint are barred.

20 **FORTY-FOURTH AFFIRMATIVE DEFENSE**

21 Plaintiffs are not entitled to general, special, compensatory, punitive or exemplary damages  
22 under Business and Professions Code sections 17200 and 17500, Civil Code section 1750 et seq.,  
23 and other statutes and regulations referenced in the Complaint.

24 **FORTY-FIFTH AFFIRMATIVE DEFENSE**

25 Plaintiffs' Complaint fails to state a claim for unlawful conduct under Business and  
26 Professions Code sections 17200 and 17500, Civil Code section 1750 et seq., and other statutes and  
27  
28

1 regulations referenced in the Complaint because Defendants completely complied with the  
2 applicable law in connection with respect to its conduct with Neurontin.

3 **FORTY-SIXTH AFFIRMATIVE DEFENSE**

4 Plaintiffs' Complaint fails to state a claim for misleading or unfair advertising or for  
5 deceptive business practices under Business and Professions Code sections 17200 and 17500, Civil  
6 Code section 1750 et seq., and other statutes and regulations referenced in the Complaint because  
7 Defendants' activities were expressly permitted by federal and state statutes and regulations and,  
8 therefore, cannot be deemed unfair, unlawful, or fraudulent.

9 **FORTY-SEVENTH AFFIRMATIVE DEFENSE**

10 Plaintiffs' claims are barred in whole or in part because Business and Professions Code  
11 sections 17200 and 17500, Civil Code sections 1750 et seq., and other statutes and regulations  
12 referenced in the complaint are insufficiently definite to provide adequate or fair notice of the  
13 conduct proscribed, in violation of the Due Process Clauses of the Fifth and Fourteenth Amendments  
14 to the United States Constitution and Article I, section 7 of the California Constitution.

15 **FORTY-EIGHTH AFFIRMATIVE DEFENSE**

16 Plaintiffs' claims are barred in whole or in part because Business and Professions Code  
17 sections 17200 and 17500, Civil Code sections 1750 et seq., and other statutes and regulations  
18 referenced in the Complaint unconstitutionally burden interstate business practices relating to  
19 prescription drugs, which are heavily regulated by the FDA. Moreover, these statutory schemes  
20 cannot be used to regulate conduct unconnected to California (see, e.g., *Norwest Mortgage, Inc. v.*  
21 *Superior Court* (1999) 72 Cal.App.4th 214.)

22 **FORTY-NINTH AFFIRMATIVE DEFENSE**

23 The Complaint's prayer for damages is barred because Plaintiffs' damages, if any, are  
24 speculative, uncertain, and incapable of being proven.



**FIFTIETH AFFIRMATIVE DEFENSE**

Defendants reserve the right to raise additional affirmative and other defenses as may be established by discovery and the evidence in this case. Defendants further reserve the right to amend their Answer and to add such counterclaims as may become necessary after reasonable opportunity for investigation and discovery.

WHEREFORE, the Defendants pray that Plaintiffs take nothing by reason of their Complaint on file herein; for its costs of suit incurred herein; and for such other relief as the Court deems proper.

Dated: April 7, 2008

Respectfully submitted,

SHOOK, HARDY & BACON L.L.P.

By:           /s/ Darolyn Y. Hamada          

Darolyn Y. Hamada

Attorneys for Defendants

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